

**CLAIMS**

Therefore, having thus described the invention, at least the following is claimed:

1           1.     A system for ligation of internal hemorrhoids, comprising:  
2           a ligator device comprised of a head assembly;  
3           a shaft assembly having opposed first and second ends, said first end mounted to  
4           said head assembly;  
5           a handle assembly mounted to said second end of said shaft assembly,  
6           and said head assembly including a removable member that stores multiple rubber  
7           bands and releases said rubber bands individually for ligation; and  
8           a three-apertured anoscope device sized and shaped to telescopically receive said  
9           head assembly.

1           2.     The system of claim 1, wherein the head assembly includes concentric  
2           inner and outer cylinders, said cylinders being slidably opposed over each other so that  
3           the outer cylinder surrounds the inner cylinder;  
4           said shaft assembly including an outer rod connected to said outer cylinder and a  
5           central rod connected to said inner cylinder,  
6           said outer cylinder being secured to the outer rod;  
7           the inner cylinder configured to accommodate two or more rubber bands about the  
8           inner cylinder on the same circumferential plane as the outer cylinder; and  
9           the inner cylinder is removable.

1           3.     The system of claim 2, wherein the inner cylinder is detachably connected  
2           to said central rod with a screw and thread attachment.

1           4.     The system of claim 2, wherein the outer cylinder is detachably connected  
2           to said outer rod.

1           5.     The system of claim 2, wherein said central and outer rods are  
2     telescopically mounted to each other.

1           6.     The system of claim 2, wherein the inner cylinder is configured for  
2     removal for reloading with multiple rubber bands and replacement within the ligator  
3     device for reuse.

1           7.     The system of claim 2, wherein the inner cylinder is configured to be  
2     removed after firing of said multiple rubber bands and replaced with another preloaded  
3     inner cylinder.

1           8.     The system of claim 2, wherein the inner cylinder is configured with a  
2     shoulder against which a disposable inner cylinder sleeve is abutted;  
3             the disposable inner cylinder sleeve configured to surround said inner cylinder;  
4             the disposable inner cylinder sleeve configured with one or more premounted  
5     rubber bands; and  
6             the disposable inner sleeve configured for removal and replacement after firing of  
7     the rubber bands with another preloaded disposable inner cylinder sleeve.

1           9.     The system of claim 1, wherein the shaft assembly is comprised of a  
2     central rod being slidably opposed by an outer rod so that the outer rod surrounds the  
3     central rod;  
4             the central rod being detachably connected to an inner cylinder of the head  
5     assembly;  
6             the central rod passing through an aperture in a firing handle of the handle  
7     assembly and being secured to said firing handle; and  
8             the outer rod being connected to an outer cylinder of the head assembly.

1           10.    The system of claim 9, wherein the central rod has a length of between  
2     approximately 6 inches and approximately 8 inches.

1           11.     The system of claim 9, wherein the central rod is secured to the firing  
2 handle with a spring clip, so that when the spring clip is released, the central rod is  
3 retracted and the inner cylinder is withdrawn within the outer cylinder and rubber bands  
4 are released from the inner cylinder.

1           12.     The system of claim 9, wherein the central rod is secured to the firing  
2 handle with a ratcheting mechanism, said ratcheting mechanism comprised of serrations  
3 along a proximal end of the central rod, a first spring used to withdraw the serrated  
4 central rod and a second spring used to stabilize and prevent forward slippage of the  
5 central rod, so that when the firing handle is activated, the central rod is retracted and the  
6 inner cylinder is withdrawn within the outer cylinder and rubber bands are released from  
7 the inner cylinder.

1           13.     The system of claim 1, wherein the handle assembly is comprised of firing  
2 handle having two opposing grips, a pivot and a spring located between said opposing  
3 grips.

1           14.     The system of claim 1, wherein the three-apertured anoscope comprises  
2 a hollow cylinder, tapered at its distal aspect and configured with three apertures;  
3 a removable obturator, comprised of a smooth, low-friction material and having a  
4 smooth, rounded tip which extends beyond the distal aspect of said hollow cylinder;  
5 a flange located at a proximal aspect of said hollow cylinder; and  
6 a handle extending from said proximal flange.

1           15.     The system of claim 14, wherein the three apertures each extend  
2 approximately one-half of a length of the anoscope along a lateral plane of the anoscope.

1           16.     The system of claim 14, wherein the apertures have a width approximately  
2 equivalent to one-sixth of a total circumference of the anoscope.

1           17.    The system of claim 14, wherein the apertures are configured to  
2 correspond to normal hemorrhoid locations in a patient, said normal hemorrhoid locations  
3 being at three o'clock, seven o'clock and eleven o'clock locations when a patient is in a  
4 prone position.

1           18.    The system of claim 14, wherein the apertures provide a means for  
2 quantitatively grading internal hemorrhoids, as the hemorrhoids may be sized relative to  
3 the width of the apertures, where each of three apertures comprises one sixth of the  
4 anoscope circumference; internal hemorrhoids may be graded as: Grade I, extending  $< 0.5$   
5 of the radius of the anoscope; Grade II extending  $> 0.5$  of the radius; Grade III extending  
6  $> 1.0$  of the radius; and Grade IV prolapsed and irreducible.

1           19.    The system of claim 14, wherein the handle is configured at an angle away  
2 from an axis of the anoscope such that when the handle is located in a twelve o'clock  
3 position, the apertures of the anoscope are properly oriented for normal hemorrhoid  
4 locations in a patient in a prone position.

1           20.    The system of claim 14, wherein the handle is configured at an angle away  
2 from an axis of the anoscope such that when the handle is located in a six o'clock  
3 position, the apertures of the anoscope are properly oriented for normal hemorrhoid  
4 locations in a patient in a supine position.

1           21.    The system of claim 14, wherein the handle is further configured with a  
2 housing for attachment of an external light source.

1           22.    The system of claim 1, further comprising a modified loading cone, said  
2 loading cone configured with a tapered front section for maneuvering of rubber bands  
3 onto the loading cone and a shouldered recess for attachment of said loading cone with an  
4 inner cylinder or inner cylinder sleeve of said head assembly.

1           23.    The system of claim 1, wherein the ligator device is configured to permit  
2 the introduction of grasping forceps through the head assembly so as to grasp tissue to be  
3 ligated and draw said tissue into the head assembly for ligation.

1           24.    The system of claim 1, wherein the ligator device is configured with a  
2 suction mechanism, wherein the central rod is hollow and the head assembly is enclosed  
3 so as to render the head assembly airtight,

4           suction is transmitted to the ligator device from a source connected to a rear  
5 aspect of the hollow central rod, and

6           suction aspirates tissue to be ligated into the head assembly for ligation.

1           25.    The system of claim 24, wherein the head assembly is enclosed with a  
2 magnifying lens so as to render the head assembly airtight and optimize visualization  
3 during a ligation procedure.

1           26.    A system for ligation of internal hemorrhoids comprising an apertured  
2 anoscope, a multiple rubber band ligator device and a modified loading cone device,  
3 wherein the anoscope is configured with multiple apertures;  
4 wherein the ligator device is configured to store multiple rubber bands on an inner  
5 cylinder and further configured to release a single rubber band at a time from the inner  
6 cylinder; and

7           wherein the modified loading cone is configured for attachment to the removable  
8 inner cylinder to facilitate loading of rubber bands onto said inner cylinder.

1           27.    The system of claim 26, wherein the anoscope is configured with three  
2           apertures,

3                   said apertures configured to correspond to normal hemorrhoid locations in a  
4           patient, thus permitting simultaneous access to three normal locations for internal  
5           hemorrhoids,

6                   said apertures extend laterally in a longitudinal direction approximately half-way  
7           along a length of the anoscope, and

8                   said apertures having a width approximately equivalent to one-sixth of a  
9           circumference of the anoscope.

1           28.    The system of claim 26, wherein the ligator device is comprised of an  
2           inner cylinder, an outer cylinder, a central rod, an outer rod, and a firing handle.

1           29.    The system of claim 28, wherein the inner cylinder and the outer cylinder  
2           are detachably affixed, the outer cylinder and the outer rod are fixedly attached, and the  
3           central rod is secured to the firing handle, such that movement of the firing handle  
4           withdraws the central rod, which in turn withdraws the inner cylinder and a single rubber  
5           band is released from the inner cylinder.

1           30.    The system of claim 28, wherein the inner cylinder is configured for  
2           removal for reloading with multiple rubber bands and replacement within the ligator  
3           device for reuse.

1           31.    The system of claim 28, wherein the inner cylinder is configured for  
2           removal after firing of said multiple rubber bands and replacement with another  
3           preloaded inner cylinder.

1           32.    The system of claim 28, wherein the inner cylinder is configured with a  
2 shoulder against which a disposable inner cylinder sleeve 9 is abutted;  
3           the disposable inner cylinder sleeve 9 configured to surround said inner cylinder;  
4           the disposable inner cylinder sleeve 9 configured with one or more premounted  
5 rubber bands; and  
6           the disposable inner sleeve configured for removal and replacement after firing of  
7 the rubber bands with another preloaded disposable inner cylinder sleeve 9.

1           33.    The system of claim 29, wherein the central rod is secured to the firing  
2 handle with a spring clip, so that when the spring clip is released, the central rod is  
3 retracted and the inner cylinder is withdrawn within the outer cylinder and rubber bands  
4 are released from the inner cylinder.

1           34.    The system of claim 29, wherein the central rod is secured to the firing  
2 handle with a ratcheting mechanism, said ratcheting mechanism comprising serrations  
3 along a proximal end of the central rod, a first spring used to withdraw the serrated  
4 central rod and a second spring used to stabilize and prevent forward slippage of the  
5 central rod, so that when the firing handle is activated, the central rod is retracted and the  
6 inner cylinder is withdrawn within the outer cylinder and rubber bands are released from  
7 the inner cylinder.

1           35.    The system of claim 26, wherein the modified loading cone is configured  
2 with a tapered front section and a shouldered recess which receives an inner cylinder to  
3 facilitate the loading of multiple rubber bands onto the inner cylinder.

1           36.    A method for ligating internal hemorrhoids, comprising the steps of:  
2           insertion of an apertured anoscope to reveal an anal canal, wherein the apertures  
3           of said anoscope correspond to the normal positions of internal hemorrhoids in man;  
4           activation of a multiple rubber band ligator device to ligate internal hemorrhoids,  
5           wherein the ligator device is comprised of an inner cylinder, an outer cylinder, a central  
6           rod, an outer rod, and a firing handle; and  
7           retraction of ligator device and anoscope.

1           37.    The method of claim 36, further comprising the step of reloading of said  
2           ligator device with rubber bands, wherein reloading is comprised of removing said inner  
3           cylinder from ligator device; connecting said inner cylinder to a cone loader; using said  
4           cone loader to load multiple rubber bands onto said inner cylinder; and reinserting said  
5           inner cylinder into said ligator device.

1           38.    The method of claim 37, wherein the step of reloading of said ligator  
2           device with rubber bands is comprised of the steps of removing said inner cylinder from  
3           ligator device and replacing said inner cylinder with a preloaded replacement inner  
4           cylinder.

1           39.    The method of claim 37, wherein the step of reloading of said ligator  
2           device with rubber bands is comprised of the steps of removing said inner cylinder from  
3           ligator device, wherein the inner cylinder is configured with a shoulder against which a  
4           disposable inner cylinder sleeve is abutted, said inner cylinder sleeve being further  
5           configured with one or more preloaded rubber bands, and replacing said inner cylinder  
6           sleeve with a preloaded replacement inner cylinder sleeve.

1           40.     The method of claim 36, further comprising the step of properly orienting  
2     said apertures in the anoscope, wherein the anoscope is configured with a handle and said  
3     handle insures proper orientation when the anoscope is inserted with the handle at a  
4     twelve o'clock position, such that said apertures correspond to the normal positions of  
5     internal hemorrhoids in man in a prone position, said normal positions of internal  
6     hemorrhoids being three o'clock, seven o'clock and eleven o'clock positions.

1           41.     The method of claim 36, further comprising the step of properly orienting  
2     said apertures in the anoscope, wherein the anoscope is configured with a handle and said  
3     handle insures proper orientation when the anoscope is inserted with the handle at a six  
4     o'clock position, such that said apertures correspond to the normal positions of internal  
5     hemorrhoids in man in a supine position, said normal positions of internal hemorrhoids  
6     being three o'clock, seven o'clock and eleven o'clock positions.

1           42.     The method of claim 36, wherein the step of operating a multiple rubber  
2     band ligator device further comprises the steps of:  
3             insertion of the ligator device through the anoscope into the anal canal;  
4             aligning the ligator device with a hemorrhoid to be ligated;  
5             retraction of tissue to be ligated into the ligator device;  
6             application of a rubber band about the tissue to be ligated;  
7             release of ligated tissue from ligator device; and  
8             retraction of ligator device.

1           43.     The method of claim 42, wherein the tissue to be ligated is retracted into  
2     the ligator device using forceps passed through a head assembly of the ligator device.

1           44.     The method of claim 42, wherein the tissue to be ligated is retracted into  
2     the ligator device using a suction mechanism, said suction aspirates said tissue into a  
3     closed, airtight head assembly of the litigation device, where said suction is transmitted to  
4     the head assembly of the ligator device via a hollow central rod.

1           45.    The method of claim 44, wherein a magnification lens is utilized to close  
2 and render airtight the head assembly, said magnification lens further configured to  
3 optimize visualization of ligation procedure.

1           46.    The method of claim 42, wherein the step of the application of a rubber  
2 band is accomplished using the ligator device, where said ligator device comprises an  
3 inner cylinder, an outer cylinder, a central rod, an outer rod, and a firing handle;  
4           the inner cylinder is detachably connected to the central rod;  
5           the central rod is secured to the firing handle with a spring clip; and  
6           activation of the firing handle releases the spring clip, where releasing the spring  
7 clip retracts the central rod and withdraws the inner cylinder within the outer cylinder,  
8 thus releasing rubber bands from the inner cylinder.

1           47.    The method of claim 42, wherein the step of the application of a rubber  
2 band is accomplished using the ligator device, where said ligator device comprises an  
3 inner cylinder, an outer cylinder, a central rod, an outer rod, and a firing handle;  
4           the inner cylinder is detachably connected to the central rod;  
5           the central rod is secured to the firing handle with a ratcheting mechanism;  
6           said ratcheting mechanism comprising serrations along a proximal end of the  
7 central rod, a first spring used to withdraw the serrated central rod and a second spring  
8 used to stabilize and prevent forward slippage of the central rod; and  
9           activation of the firing handle releases the first spring, where releasing the first  
10 spring retracts the central rod and withdraws the inner cylinder within the outer cylinder,  
11 thus releasing rubber bands from the inner cylinder.

1           48.    A ligator device for applying bands to internal organs of animal life  
2 comprising:  
3           a head assembly for protruding into the animal including an inner cylinder and an  
4 outer cylinder arranged in telescopic slidable relationship with respect to each other,  
5           said inner cylinder including an end portion for protruding beyond said outer  
6 cylinder and supporting thereabout a plurality of rubber bands, and said outer cylinder  
7 having an inner dimension for engaging the rubber bands mounted on said end portion of  
8 said inner cylinder and urging the rubber bands off said end portion of said inner cylinder  
9 when said outer cylinder is slid about the inner cylinder, and  
10          a shaft assembly including a central rod having a first end connected to said inner  
11 cylinder and a second end for protruding out of the animal, and an outer rod having a first  
12 end connected to said outer cylinder and a second end for protruding out of the animal, so  
13 that the inner and outer cylinders can be manipulated in the animal by movement of said  
14 shaft assembly from outside the animal.

1           49.    The ligator device of claim 48, and further including a handle mounted to  
2 said second ends of said central and outer rods for manipulating said inner and outer  
3 cylinders.

1           50.    The ligator device of claim 48, wherein said first and second cylinders  
2 define an elongated passage through which surgical instruments can pass, and said handle  
3 projects away from said elongated passage so as to not interfere with the passing of  
4 surgical instruments through said elongated passage.

1           51.    The ligator device of claim 49, and wherein said handle includes a trigger  
2 for engaging and moving said central and outer rods with respect to each other, so that  
3 said inner and outer cylinders also move with respect to each other and urge a rubber  
4 band off said inner cylinder.

1           52.    The ligator device of claim 48, wherein said first and second cylinders  
2 define an elongated passage through which surgical instruments can pass.

1           53.    The ligator device of claim 48, and further including a rubber band loading  
2 cone defining a mandrel configured to fit in said end portion of said inner cylinder and a  
3 tapered head of a breadth corresponding to the exterior breadth of said inner cylinder and  
4 suitable for transferring rubber bands from said tapered head onto said end portion of said  
5 inner cylinder

1           54.    The ligator device of claim 48, and further including a three-apertured  
2 anoscope for insertion in a cavity of an animal defining an internal passage configured to  
3 slidably receive said outer cylinder.

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